REMARKS

The Examiner is thanked for the courtesy of granting an interview. The Examiner is also thanked for withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 1-16 in view of WO 00/78292 to Serpelloni, *et al*. In the Office Action, Claims 1-16 are pending and have been rejected. Claims 1 and 4 are amended herein to a disintegration time period of within 47 seconds and to exclude specific celluloses. Via this amendment, Claim 1 has also been amended to correct misspelling of the word "mannitol".

Applicants have carefully reviewed the Examiner's Office Action dated July 5, 2007, rejecting Claims 1 to 16 under 35 U.S.C. §112, first paragraph as failing to respond to the written description requirement. According to the Examiner, there is insufficient disclosure to establish that, the inventor(s) at the time the application was filed, had position (sic) of the negative limitation "no cellulose."

Applicants traverse this rejection. The Examiner has not made a *prima facie* case of no written description. The Examiner has not met the initial burden of presenting evidence or reasons why persons of skill in the art would not recognize in the specification disclosure a description of the invention defined by the claims. None of the Examples 1-13 of the present invention utilize cellulose, whether it be microcrystalline cellulose or any other type of cellulose. Moreover, in the Comparative Examples, crospovidone is **replaced** with cross-linked carboxymethyl cellulose, sodium starch glycolate, and low substituted hydroxypropyl cellulose. Therefore, the tablets of the present application have "no cellulose" and one skilled in the art, reading the specification, would

immediately discern the limitation at issue. The Examiner cites *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). Applicants submit that reliance on this case is misplaced. *Purdue* requires the specification to "emphasize", "motivate", or "describe" the "importance" of the invention. In *Purdue*, the court found nothing in the Examples or specification that would suggest to one skilled in the art that the C_{max}/C_{24} ratio was an important defining quality of the formulation. The Examiner also cites I*n re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967) where the issue was one of fact as to whether the specification convey clearly to those skilled in the art that the applicants invented the specifically claimed compound. In the present invention, in every embodiment, there is no cellulose. Additionally, other ingredients are described in paragraph [0021] and [0023] of the present application (*see* publication no. 2002/0071864) as sweetening agents, lubricants, organic acids, effervescent agents, lubricants, diluents, and flavors, none of which include any cellulose. Therefore, the original disclosure of the present invention conveys the concept now claimed. Moreover, other celluloses than microcrystalline cellulose replace one of the required ingredients in Comparative Examples, thereby providing support for "no cellulose" throughout the specification. That is, cross-linked carboxymethylcellulose and low-substituted hydroxypropyl cellulose were used in the comparative examples. Additionally, cellulose is a generic term which includes, microcrystalline cellulose, cross-linked carboxymethylcellulose and low-substituted hydroxypropyl cellulose.

For additional support, Applicants previously submitted an Inventor Affidavit with experimental data or arguments or references which distinguish the present invention. Table 1 of that Affidavit shows that the addition of cellulose as in tablets B to D increases the disintegration time.

However, to advance prosecution of the present case, Claims 1 and 4 have been amended to specifically exclude cellulose selected from the group consisting of microcrystalline cellulose, low-substituted hydroxypropyl cellulose, and carboxymethyl cellulose. No new matter is added via this amendment. Support for this Amendment is found in the specification and Comparative Examples 1-13.

Claims 1 and 4 are additionally amended herein to indicate that the tablets of the present invention disintegrate in the oral cavity within 47 seconds. Support for this is found in the specification at Examples 1-13. With the exception of Comparative Example 6.1, each Comparative example where celluloses were substituted for crospovidone, the disintegration time is greater than 47 seconds. Comparative Example 6.1 is directed to cisapride, the solubility of which depends very much on the surrounding pH. The solubility of cisapride is the highest in a strongly acidic medium at pH 1 to 2, such as for example in gastric juice. The solubility diminishes rapidly when the pH of the (physiological) medium increases, for example in the oral cavity where the pH is between 6.78-7.34 (*See* Aframian DJ. The Distribution of Oral Mucosal pH Values in Health Saliva Secretors. Oral Diseases 12:420-423 (2006)). Similarly, while the tablet of Example 11 does disintegrate within 47 seconds, it also is directed to a different active ingredient, i.e. sildenafil. Sildenafil is a hydrophobic active ingredient has an intrinsic aqueous solubility of less than about 1 mg/mL. Hydrophobic active ingredients, such as sildenafil present delivery challenges due to poor aqueous solubility and slow dissolution rate.

In view of the foregoing amendments and discussions, it is respectfully submitted that the present invention as defined in the pending Claims 1 to 16 is in full compliance with all the statutory requirements, and therefore, it is earnestly requested that the Examiner's rejections be withdrawn and the pending claims be allowed in their present form.

Any fee due with this paper, may be charged to Deposit Account 50-1290.

Respectfully submitted,

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